

This Page Is Inserted by IFW Operations  
and is not a part of the Official Record

## **BEST AVAILABLE IMAGES**

Defective images within this document are accurate representations of the original documents submitted by the applicant.

Defects in the images may include (but are not limited to):

- BLACK BORDERS
- TEXT CUT OFF AT TOP, BOTTOM OR SIDES
- FADED TEXT
- ILLEGIBLE TEXT
- SKEWED/SLANTED IMAGES
- COLORED PHOTOS
- BLACK OR VERY BLACK AND WHITE DARK PHOTOS
- GRAY SCALE DOCUMENTS

**IMAGES ARE BEST AVAILABLE COPY.**

**As rescanning documents *will not* correct images,  
please do not report the images to the  
Image Problem Mailbox.**

N938

U.S. PATENT APPLICATION OF  
ROBERT E. SIMONSON

relating to

NON CANNULATED DILATORS

"Express Mail" mailing label number EK755961259US  
Date of Deposit Oct. 20, 2001  
I hereby certify that this paper or fee is  
being deposited with the U. S. Postal Service  
"Express Mail Post Office to Addressee," service  
under 37 CFR 1.19 on the date indicated above and  
is addressed to the Commissioner of Patents and  
Trademarks, Washington, DC 20231.

NORMAN FRIEDLAND  
Norman Friedland

**Description**  
**NON CANNULATED DILATORS**

**Technical Field**

5        This invention relates to dilation systems and apparatus used in performing minimal invasive surgery and particularly in an application of the instrument in initiating the surgery where dilators are utilized to enlarge the area where the surgery will be performed on a patient.

**Cross References**

10        This invention relates to a patent application filed on even date by the applicant of this patent application and entitled "CONFIGURED AND SIZED CANNULA" and bearing Attorney Docket No. N908.

**Background of the Invention**

15        As is well known by those skilled in this technology minimally invasive approaches for performing spinal surgery such as laminotomy, medial facetectomy, foraminotomy, nerve root retraction, discectomy and the like,

FOIEUO 10024324 103004

require an initial cut into the skin and tissue of the patient before a series of increasingly larger diameter dilators are inserted to widen the area where the surgery will be performed. As is well known and as described in U.S. Patent No. 6,159,179 granted on December 12, 2000 to the inventor of this patent application and entitled "Cannula and Sizing and Insertion Method", a guide wire with a sharpened tip to percutaneously pass through the muscle and engage a target of bone or vertebral disc is typically used. The first dilator is then passed over the guide wire and down to the target. Unfortunately, this method is fraught with a potential danger to the patient. Because the guide wire is relatively thin where it is able to pass through the muscle and ligamentous anatomy, it can protrude into the spinal canal and hence, cause injury to the delicate neural anatomy. If the misplaced guide wire is not detected before the dilators are inserted, catastrophic injury, such as permanent disablement of the patient can occur. Obviously, since this is a potential problem as it is considered a risk to a candidate needing minimally invasive surgery, the use of this type of surgery has been stifled and its potential to grow which ultimately is for the benefit of all patients requiring this type of surgery is thwarted. Of course, the surgical target does not

involve the neural anatomy in every spinal surgery and hence, in these situations the use of a guide wire is not a potential hazard and can be safely used.

5 I have found that I can obviate the problems noted in the above-  
paragraphs particularly in minimally invasive spinal surgery where it is  
necessary to access and decompress the spinal nerves and where safety is of  
a major concern. This invention utilizes a series of muscle dilators in which the  
first dilator is solid with a design that permits accurate passage through the  
muscle tissue without the assistance and risk of a pre-placed guide wire. The  
10 tip of this inventive dilator is judiciously designed to part and pass through the  
muscle fibers and allows the surgeon to maintain a course directed toward the  
intended anatomical target. Because of the inventive dilator when the muscle  
is passed in the insertion procedure the likelihood for the surgeon forcing the  
inventive dilator through the ligamentum flavum and continue to pass into the  
15 spinal canal is avoided. My invention contemplates dimensioning the non  
cannulated dilator such that the surgeon when performing the procedure will  
get a "feel" as the instrument passes through the tissue and muscle of the  
patient so that the surgeon will have a good sense of what portion of the

anatomy is being penetrated. This will help in assisting the surgeon in avoiding the spinal canal.

### **Summary of the Invention**

5 This invention relates to an improvement in the instrument utilized in minimal invasive surgery of the type that utilize dilators.

10 A feature of this invention is a non-cannulated dilator that is made from a solid elongated body having a tip portion at the distal end and a tool engaging portion at the proximal end. The outed diameter dimension of the non-cannulated dilator is critical in that the diameter is sufficiently large so that the instrument is stiff and rigid and greater than one (1½) mm and that the tip is discreetly blunted or rounded.

The foregoing and other features of the present invention will become more apparent from the following description and accompanying drawings.

### **15 Brief Description of the Drawings**

These figures merely serve to further clarify and illustrate the present invention and are not intended to limit the scope thereof.

10024221-103001

Fig. 1 is a cut-away view of the anatomy of a patient with the inventive non-cannulated dilator inserted into the patient to the target area;

Fig. 2 is a perspective view of a series of sequentially enlarged diameter dilators that are inserted over the non-cannulated dilator in order to  
5 widen the cavity to insert the cannula;

Fig. 3 is an elevated view of the non-cannulated dilator showing the details of this invention;

Fig. 4 is an end view of the proximal end of this invention illustrating the blunted tip; and

10 Fig. 5 is an end view of the proximal end of this invention illustrating the tool engaging portion.

#### **Detailed Description of the Invention**

15 While this invention in its preferred embodiment discloses ovoid shaped dilators, it is to be understood as those skilled in this art will appreciate, any shaped dilators and cannulas can be utilized with this invention. However, the initial dilator is non-cannulated, i.e. it is a solid elongated cylindrical body with a judiciously shaped pointed tip at the distal

10024331-10301  
F00E0F "F2242007

end and a tool receiving tip at the proximal end. Obviously, it is not imperative that the non cannulated dilator be cylindrical or circular in cross section as ovoid or other cross sectional shapes can be substituted therefor without departing from the scope of this invention. The term "cavity" as used herein refers to the opening in the patient formed by the non cannulated dilator, dilators and dilator retractor and becomes a working channel when the non cannula dilator and dilators are removed from the dilator retractor for the surgeon to use to perform the minimal invasive surgery. the terms "cannula" and "dilator retractor" as used herein have the same meaning and are used interchangeably.

The invention can best be seen by referring to all the Figs where the inventive non-cannulated dilator is generally illustrated by reference numeral 10 consisting of a cylindrical solid elongated body 12, a tool receiving portion 14 at the proximal end, and the pointed cutting tip portion 16 at the distal end. In accordance with this invention the diameter of the cylindrical solid elongated body 12 is greater than one and a half (1½) mm and preferably substantially equal to five (5) mm. The very end of the tip portion 16 is rounded and defines a blunt portion 20 as opposed to a needle type shape that



would be found, for example, on the heretofore utilized guide wire. The preferred dimensions are shown in Figs. 3, 4 and 5. As follows:

- 5                   A = 171.5 (millimeters) (6.750 inches)
- $\theta$  = 16 degrees
- B = 5.28 mm (0.208") diameter
- C = 1.0 mm (0.039") diameter
- D = Hex shape and extends 1.27 mm (.50") axially

10                   While these dimensions are disclosed in the preferred embodiment as being preferred, as one skilled in this art will recognize that these dimensions can be slightly modified without departing from the scope of this invention. However, it is abundantly important that the very tip 20 of the tip portion 16 be blunted and the diameter of the cylindrical body 12 be sufficiently large so that the tissue and muscle of the area being penetrated affords a resistance

15                   whereby the surgeon will have a feel as the instrument penetrates different portion of the anatomy. In comparison with a guide wire as used heretofore, the non-cannulated dilator 10 of this invention is relatively rigid and will not bend or flex when attempted to be bent under the normal force of the human hands as opposed to the guide wire that will bend and flex under the same

20                   force conditions.

After a small stab wound is made at the entry point, as shown in Fig.

1, the non cannulated dilator 10 is "worked" by forcing and partially rotating the dilator with the use of a tool (not shown) attached to the tool engaging end 14 until it reaches its target, and in this instance, until it reaches the inferior edge of the superior lamina. Obviously, under circumstances where the tissue and muscle do not pose a restrictive force that is sufficient to justify the use of a tool when being inserted, the non cannulated dilator may be inserted without the use of a tool. As is apparent from Fig. 1, the tip portion 16 is designed to pass through the muscle fibers and allows the surgeon to maintain a course directed toward the intended anatomical target.

Once the target has been reached, each of the dilators 18 are sequentially inserted over the non cannulated dilator in the order of the smallest to the largest diameter dilator and likewise are worked with the use of a tool until the target is reached. The non cannulated dilator 10 can be marked with a graduated scale that the surgeon can use to select the proper sized dilator retractor or cannular 20. The cannula or dilator retractor 20 is inserted over the last of the dilators 18 whereby the surgeon then has access to the target in order to proceed with the surgery or stated another way the dilator retractor 20 defines a working channel to accommodate all of the

instruments used in the surgical procedure.

Obviously, in the procedure for obtaining the working channel enumerated in the immediately above paragraph, the inventive non-cannulated dilator 10 replaces the heretofore utilized guide wire avoiding or at least avoiding the likelihood of passing through the ligamentum flavum and into the spinal canal.

Although this invention has been shown and described with respect to detailed embodiments thereof, it will be appreciated and understood by those skilled in the art that various changes in form and detail thereof may be made without departing from the spirit and scope of the claimed invention.

I claim: